UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460

MEMORANDUM **March 10, 2010**

Subject: Response to Dow AgroSciences Comments on the Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered species and Drinking Water Assessments for Tebuthiuron (PC Code 105501; DP Barcode 372445)

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The Environmental Fate and Effects Division (EFED) has reviewed all of the Dow AgroSciences comments that were relevant to the "Registration Review–Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered species and Drinking Water Assessments". The following provides EFED's responses to all these comments.

The Environmental Fate and Effects Division Responses to Dow AgroSciences Comments

Dow AgroSciences Comment: Risk to Threatened and Endangered Species already addressed through Section 7 Consultation

"The Agency has stated that an evaluation of potential risk to Threatened and Endangered Species (TES) will be undertaken as a part of the EPA registration review; however, this work has already been done. In their proposal for the use of herbicides in vegetation management programs on BLM-managed lands, the federal Bureau of Land Management (BLM) has recently finalized their "Programmatic Environmental Impact Statement Vegetation Treatments Using Herbicides on Bureau of Land Management Lands in 17 Western States" (the "PEIS"). The BLM PEIS hazard evaluation is generally conservative and exposure estimates are performed with tools using calculations and procedures similar to EPA methods. Under Section 7 of the ESA, BLM entered into a consultation agreement with the NOAA National Marine Fisheries Service and the US Fish and Wildlife Service, who concurred with BLM's findings of "may affect, but not likely to adversely affect," with specified standard procedures and protective measures. At the local level, BLM has consultation streamlining agreements in place to rapidly conclude consultations for local vegetation control programs. Because of this comprehensive effort by BLM, it is suggested that reference to the BLM PEIS can fulfill a majority of EPA's obligations for ESA Section 7 consultation for the Registration Review of tebuthiuron. Dow AgroSciences has summarized this document for the convenience of EPA and submitted it on April 23, 2009 as MRID No. 47736301 "Tebuthiuron - Use of Bureau of Land Management Assessments to Fulfill ESA consultation Requirements," this document has also been submitted to the tebuthiuron registration review docket."

EFED Response

EFED will evaluate the results, tools, and procedures provided in the submitted document entitled "*Tebuthiuron - Use of Bureau of Land Management Assessments to Fulfill ESA Consultation*". However, the scope of uses considered for the consultation conducted on BLM-managed lands is different than the scope of uses considered for the registration review assessment. Because the registration review assessment will consider uses both on and off BLM-managed land, the previous consultation, which considered only tebuthiuron uses on BLM-managed lands, is not fully applicable to registration review.

Dow AgroSciences Comment: Aquatic Field Dissipation study (OPPTS Test guideline No. 835.6200; 164.2)

"As noted in the 1994 RED and the June 15, 2009 Memorandum entitled *Registration Review- Preliminary Problem Formulation for Ecological Risk and Environmental Fate, Endangered Species and Drinking Water Assessment for Tebuthiuron* (PC Code 10550 I; DP Barcode D363982; docket item EPA-HQ-OPP2009-0327-0005), tebuthiuron is stable in water through hydrolysis and photolysis and has relatively long half-lives in aerobic

and anaerobic aquatic metabolism studies. These data indicate that little or no useful information could be obtained from an aquatic field dissipation study. Further, Dow AgroSciences removed the use on ditch banks in the early 1990s and as the only aquatic use, the aquatic dissipation study for tebuthiuron was no longer required. The June 15, 2009 Memorandum states that current labels suggest that there is a use for drainages and therefore the aquatic dissipation study could now be required. Dow AgroSciences has thoroughly reviewed tebuthiuron labeling and cannot find any recommendation for use on drainages. Further, Dow AgroSciences' staff goes to great effort to prevent such use and will visit the application site prior to treatment if there is any question about potential water impact. In fact, one of the key uses of tebuthiuron is improving grazing away from water sources and critical riparian habitats. By opening up brushland away from water, tebuthiuron can impact the distribution of livestock on rangeland by improving access and ease of movement for both livestock and wildlife and reduce the pressure on riparian habitat from grazing. If there is any section of the tebuthiuron end-use labels that is unclear, Dow AgroSciences would certainly consider a modification of the label language to make this point clearer."

EFED Response

For registration review, EFED will consider all registered uses. Currently the ditch banks use is included on the label assigned the registration number of 34913-10. Thus, the Aquatic Field Dissipation study is still required.

Dow AgroSciences Comment: Marine/estuarine Fish acute toxicity (OPPTS Test guideline No. 850.1075; 72-3)

"This data requirement was waived in a Memorandum dated 27-Feb-1987 to Mary Erumsele (RD) from Carol Natella (EEB) (attached); the waiver was reiterated in the RED. The Agency determined that the study was not required in light of tebuthiuron's extremely low toxicity to freshwater fish and marine and freshwater invertebrates."

EFED Response

Although the Tebuthiuron RED issued in June 1994 waived the acute toxicity data requirement for estuarine/marine fish species due to "the demonstrated low toxicity of tebuthiuron to freshwater fish as well as marine and freshwater invertebrates", there remains uncertainty regarding the potential risks to estuarine/marine fish in the absence of an acceptable study. The available acute invertebrate data suggest that estuarine/marine invertebrates are approximately 4.8 times more sensitive than freshwater invertebrates (based on the most sensitive estuarine/marine and freshwater invertebrate acute LC_{50} values of 62 mg/L and 297 mg/L, respectively). If the invertebrate ratio of 4.8 is applied to the freshwater fish acute toxicity LC_{50} value of 106 mg/L, the resulting estimated estuarine/marine fish LC_{50} would be 22 mg/L. Assuming an acute estuarine/marine fish LC_{50} value of 22 mg/L, predicted peak EECs for tebuthiuron of 1.1 mg/L would be required to exceed the LOC. The 1994 RED estimated that tebuthiuron could potentially attain these concentrations in shallow water bodies (see Table 1). If estuarine/marine fish are in fact more sensitive to tebuthiuron than estimated based on the aquatic invertebrate data, predicted surface water concentrations of <1.1 mg/L would result in LOC exceedances.

Table 1. Estimated environmental concentrations (EEC) of tebuthiuron in a one acre body of water of various depths based on the Tebuthiuron 1994 RED.	
Depth of Water	**Peak EEC Concentration (mg/L)**
6 inches	2.2
1 foot	1.1

In addition, there are physiological differences between marine/estuarine fish and freshwater fish that may cause marine/estuarine fish to be more sensitive to the toxicity of tebuthiuron. Therefore, submittal of an acute estuarine/marine fish toxicity study per OPPTS guideline 850-1075 would reduce the uncertainties associated with the lack of available data and presumed risk to estuarine/marine fish.

Dow AgroSciences Comment. Bivalve acute toxicity on shell deposition and embryo larvae study (OPPTS Test guideline No. 850.1025; 850.1055; 72-3 (b))

"A study was previously submitted (MRID 00041684) and declared as meeting guideline requirements in the 27-Feb-1987 Memorandum and reiterated as acceptable in the RED. Tebuthiuron was practically nontoxic to Eastern oyster embryos (LC_{50}>180 and <320 ppm)."

EFED Response

EFED concurs with Dow AgroSciences regarding the previously submitted embryo larval toxicity study (MRID 00041684). This study is classified as acceptable and fulfills the guideline requirement for acute embryo larval toxicity studies. However, the 40 CFR also requires a bivalve acute toxicity shell deposition study (Guideline no. 72-3(b)/850.1025) for pesticides that may potentially enter waterways. Additionally, the tebuthiuron use patterns include a multitude of use areas including pasture and rangeland and a variety of non-food crop sites, such as airports/landing fields, outdoor industrial areas, non-agricultural rights-of-way, fencerows, hedgerows, uncultivated areas/soils, and under paved roads and sidewalks in areas where no future landscaping is planned. Many areas associated with these non-agricultural use patterns may occur in close proximity to a marine/estuarine habitat of mollusks that could be exposed to tebuthiuron. Additionally, tebuthiuron has a high potential to move through soil from the original site of application to estuarine/marine systems. Thus, EFED requires the submission of a bivalve acute toxicity on shell deposition study per guideline-72-3(b)/(850.1025).

Dow AgroSciences Comment: Crustacean acute toxicity (OPPTS Test guideline No. 850.1035; 850.1045; 72-3(c))

"A study with pink shrimp was previously submitted (MRID 00041684) and declared as meeting guideline requirements in the 27-Feb-1987 Memorandum and reiterated as acceptable in the RED. Tebuthiuron was found to be slightly toxic in the test (LC_{50}= 62 ppm)."

EFED Response

EFED concurs with Dow AgroSciences regarding the previously submitted crustacean acute toxicity study testing the pink shrimp (MRID 00041684). This study has been reviewed and is classified as acceptable for fulfilling the acute crustacean toxicity study

guideline requirement.

Dow AgroSciences Comment Freshwater fish early life-stage study (OPPTS Test gnideline No. 850.1400; 72-4(a))
"Two studies were previously submitted, on fathead minnow (MRID 00090084) and rainbow trout (MRID 00090083). Both studies determined to meet guideline requirement in the 27-Feb-1987 Memorandum and reiterated as acceptable in the RED. MATC values were >9.3 and <18 ppm and >26 and <52 ppm for minnow and trout, respectively."

EFED Response
EFED concurs with Dow AgroSciences regarding the previously submitted fathead minnow (MRID 00090084) and rainbow trout (MRID00090083) studies. These studies have been reviewed and classified as acceptable for fulfilling the guideline requirement for a freshwater fish early life-stage study (OPPTS Test guideline No. 850.1400; 72-4(a)).

Dow AgroSciences Comment: Freshwater invertebrate life cycle study (OPPTS Test guideline No. 850.1300; 72-4(b))
"A study on *Daphnia magna* was previously submitted (MRID 00138700; also cited as NAOTEBOI) and declared as meeting guideline requirements in the 27-Feb-1987 Memorandum and reiterated as acceptable in the RED. The MATC for growth and fecundity was found to be >21.8 and <44.2 ppm."

EFED Response
EFED concurs with Dow AgroSciences regarding the previously submitted freshwater invertebrate life cycle study testing *Daphnia magna* (MRID 00138700). This study has been reviewed and classified as acceptable for fulfilling the guideline requirement for a freshwater invertebrate life cycle study (OPPTS Test guideline No. 850.1300; 72-4(b)).

Dow AgroSciences Comment: Tier II Seedling emergence toxicity study (OPPTS Test guideline No. 850.4100; 123-1a)
"A study was previously submitted (MRID 41066901. transmittal of 4/18/1989 and PR Notice 86-5 compliance notice of *4125/1989)* and declared as an acceptable Tier II study in the RED. Although the study title states "Tier I," this study is a full dose-response (6 dose levels) experiment on 10 plant species and thus is a true Tier II study. The study employed a pre-emergence application. This is appropriate for the biological characteristics of tebuthiuron where the material requires activation by rainfall for weed control activity as the primary uptake mechanism for tebuthiuron is through plant roots. Although the study was carried out with TGAI solutions (not a TEP as stipulated in the updated 40CFRI58), this would have little impact. For the Spike 20P Specialty Herbicide (granular) formulation, the product contains only active ingredient and inert clay carrier and thus the TGAI solution results are worst-case (as release from the granules would reduce the short-term effects seen in the testing). In the case of the wettable powder end-use product (Spike' 80DF Specialty Herbicide), the formulation contains primarily active ingredient and clay carrier, with small amounts of other ingredients included to improve the handling characteristics of the dry material. The tank-mix solution, when applied to

soil, would partition into its separate components and essentially act in the environment as the TGAI. Therefore, further plant testing is not scientifically warranted for either formulation type."

Dow AgroSciences Comment: Tier II Seedling vegetative vigor (OPPTS Test guideline No. 850.4150; 123·1b)

"The study cited in the previous point (MRID 41066901) also included vegetative vigor measurements."

EFED Response

Because of the lack of either a Tier II seedling emergence study testing the TEP of tebuthiuron (OPPTS Test guideline No. 850.4100; 123-1a) or a Tier II vegetative vigor study testing the TEP of tebuthiuron (OPPTS Test guideline No. 850.4150; 123·1b), EFED is currently unable to conclude with certainty that the TEP of tebuthiuron will not pose a more significant risk to nontarget terrestrial plants than the TGAI. The registrant cited two products (Spike 20P Specialty Herbicide (20% a.i.) and Spike' 80DF Specialty Herbicide (80% a.i.) to support the bridging of the TGAI study to a TEP study. However, additional formulations are also available with percent active ingredients that range from 1% to 80%. Studies on the TGAI will likely be more applicable to some formulations and less applicable to other formulations. An acceptable study on a TEP remains a data gap.

Dow AgroSciences Comment: Avian reproductive toxicity study (testing exposure concentrations ranging from >100 ppm to at least up to 810 ppm) (OPPTS Test guideline No. 850.2200; 71·4)

"Two avian reproduction toxicity studies are available for tebuthiuron (MRID 00104243 and 00093690 for bobwhite quail and mallard duck, respectively): the studies indicated low toxicity with both NOEL values > I00 ppm, the highest concentration tested. In the preliminary problem formulation for ecological risk assessment, the Agency anticipated that application of tebuthiuron at the highest envisaged rate of 6 lb. ai/A may lead to upper bound residues on small insects of 810 ppm which is higher than the dietary concentrations tested in the existing avian long-term studies. It should however be considered that the residues used in T-REX for insects are derived from the Hoerger and Kenaga (1972)' data which has been modified by Fletcher et al. (1994)3. These data are based on residues measured on vegetation as a surrogate for insects with similar surface area to mass ratios. Residues on real insects have been measured in recent European studies and are summarized in an opinion prepared by the European Food Safety Authority (EFSA) Plant Protection products and their Residues (PPR) Panel" for use in risk assessment. Since during applications of tebuthiuron the spray will be directed to bare ground, insects that may be exposed are those present on the soil surface. The mean and 90'" percentile residues per unit dose measured on ground dwelling invertebrates without any plant interception in the European studies are 7.5 and 13.8 ppm per kg ai/ha applied, respectively (Appendix 14, Table I of the EFSA report: attached for your convenience with this document). Conversion of these values to ppm per lb. ai/A applied (i.e., xU2/) leads to mean and 90th percentile residues per unit dose of 8.41 and 15.5 ppm, respectively. For an application of tebuthiuron at 6 lb. ai/A, the mean and 90mpercentile

predicted residues on soil insects thus are 50.4 and 92.8 ppm, respectively, Both of these values are below the 100 ppm NOEL values from the avian long-term studies, indicating that the existing information on avian reproductive toxicity should be regarded as sufficient for the long-term risk assessment of tebuthiuron."

EFED Response

EFED will examine the information that Dow AgroSciences has provided regarding the European studies mentioned in the above comment. However, the Fletcher nomogram remains the standard method used to estimate potential exposures to pesticides. Therefore, submission of a guideline study that exposes birds at or above levels estimated to be found on potential food items of birds remains a data gap. Without submission of such a study, EFED cannot preclude potential risks to birds. The maximum allowable single application on current labels is currently 6 lbs a.i./Acre as reported in the problem formulation, which will result in estimated concentrations on avian food items that range from 90 ppm to 1440 ppm. Therefore, a dietary toxicity study conducted at up to 100 ppm cannot be used to preclude risks to birds that may be exposed to pesticide concentrations at >100 ppm.